

### **REMARKS/ARGUMENTS**

In response to the Office (Final) Action dated October 4, 2007, Applicant offers the above specified amendments to the claims and the specification which it requests be entered, as they put the application in form for allowance or, at the very least, in better form for appeal for the reasons set forth below.

Claims 1-14, previously presented, stand finally rejected.

Claims 1-8 are submitted herewith in amended form, along with new claim 15. Claims 9-14 have been canceled as directed to the same inventions of claims 1-8 and 15.

Before pointing out in detail how the pending claims include limitations that are not found in the prior art nor made obvious thereby, Applicant will point out the features of its invention that appear in the claims and that set it apart from the prior art.

#### **Summary of Invention**

The importance and function of the seal of the invention is best illustrated in Fig. 3 where the vent 23 in the lid 14 of the sterilization container 10 includes vent holes 24 for the introduction of sterilization media into the container 10. A filter 36 is interposed over the vent 23, inside the container and secured in place by a cover 37 that has vent holes 38. In order to prevent contaminants from entering the sterilization container 10 by way of the vent, it is essential that the only pathway from outside the container to inside the container through the vent 23 be through the filter 36 (and not around it). In order to meet this requirement, it is necessary for the filter 36 to

be so sealed to the planar container member that includes the vent 23 that no contaminant is able to pass between the filter 36 and the vent 23 and thereby enter the sterilization container 10 without first passing through the filter 36. Fig. 5 best illustrates how the seal of the invention operates to limit the path from the exterior of the container 10 to the interior of the container 10 to one through the filter 36. An essential component of the sealing arrangement is a pliable gasket 26 that resides wholly within the vent recess 26 in the container lid 14. When secured in place (Fig. 5), the filter 36 is compressed between the gasket in recess 36 and cover ridge 43 and thereby secured in place and, at the same time, forms a seal that surrounds the vent 23 and restricts the path to the interior of the container 10 through vent 23 through filter 36.

As is well known in the art, it is necessary to frequently change the filter 36 in a sterilization container and it is a common practice to clean the sterilization container at the same time that the filter is changed. A typical gaskets that extend above the plane of the vent will be exposed during such filter changes and cleaning operations and, thus, not infrequently damaged in a way that compromises its ability to seal out contaminants.

As best seen in Fig. 4, the gasket 27 has a concave cross-section to conform to the contour of the recess 36 in which it wholly resides and by which it is far less exposed to damage during the changing of the filter and/or the cleaning of the container 10.

Furthermore, in Applicant's invention, when the seal is fully implemented with the cover plate 37 forced against the gasket 26 and the

recess 26, the space between the vent cover 37 and the vent 23 is substantially greater than the thickness of the filter 36 (see Fig. 5). This relationship establishes an interstitial space 46 which facilitates the lateral movement of steam or other sterilization medium to traverse the misaligned holes 24 and 38 in the vent 23 and the cover vent 37, respectively, and thus facilitate free flow of sterilization media.

**Claim 1**

Claim 1, as amended, clearly calls out, in a series of limitations, the ridge around the cover vent and the recess around the interior container planar member, the filter that overlies both the vent and vent recess and the gasket that resides wholly within that recess.

**Rejection: Claims 1-12 Under 35 U.S.C. 103(a) Williams ('913)/Lorenz ('311)**

The Examiner acknowledges that "Williams ('913) does not appear to specifically teach that the vent recess (54) is formed in an interior container planar surface wherein said vent recess (54) is concave relative to the interior planar surface and said seal ridge is forced against a gasket and the sheet filter to form a seal nor that said gasket is secured wholly within said vent recess where it is protected against damage."

Since the elements in Claim 1 admittedly not present in Williams '913 are at the heart of Applicant's invention, it is highly doubtful that Williams '913 establishes a *prima facie* case of obviousness.

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### **Williams ('913)**

With reference to Williams, the elements labeled 54 and 77 in Fig. 6 of Williams do not and cannot form a seal and are not provided for that purpose. As set forth in Col. 5, starting at line 58, Williams states: "upper barrier plate member 70 has a peripheral recess groove 77 disposed for registration with the corresponding concave surface provided by the recess groove 54 in cover member C, as aforesaid." Thus, the purpose of elements 54 and 77 in Williams is not to form a seal, but rather merely for purposes of registration. This is further borne out by the fact that the upper barrier plate member 70 is fixedly attached to the side wall of the cover member C by structures 80, 82 and 84 on one side and 86 and 88 on the other side. (Col. 5, line 62 to Col. 6, line 2.) Being locked in that position, it is not possible for recess groove 77 to be forced into recess groove 54 so as to form a seal therewith. Thus, the recess grooves 54 and 77 do not prevent media that enters apertures 50 and cover member C from entering the interior of the sterilization container without passing through the filter 85. Put quite simply, the recesses 54 and 77 are not provided to form a seal and any characterization or reconstruction of those elements as a seal would so transcend the teachings of Williams as to amount to nothing more than hindsight reconstruction.

It is not surprising that the no sealing arrangement is described in Williams, as Williams' invention is not directed to a seal or a filter, but rather to the locking mechanism which secures the lid of the container to the body of the container (see Col. 1, lines 10-14 and the claims).

Thus, to emphasize that which the Examiner has acknowledged, the following elements of Applicant's invention as set forth in claim 1 are not disclosed in the primary reference of Williams '913:

(a) a vent recess formed on the interior surface of a container planar member surrounding a vent;

(b) a gasket secured wholly within said vent recess where it is protected against damage;

(c) a generally planar filter cover member having a cover vent and a planar surface with a cover ridge that surrounds the cover vent;

(d) a sheet filter overlying the vent and vent recess;

(e) wherein when the cover filter cover member is secured in place, the cover ridge is forced against the sheet filter which, in turn, is forced against the gasket to form a seal around the vent.

In fact, Williams '913 does not teach a seal that surrounds the filter.

As to the elements (a)-(e), it is stated (at pages 4-5 of the Office Action), without any apparent support beyond the Examiner's opinion, that it would have been obvious to reconstruct Williams to meet the elements of claim 1. To accomplish this, it would be necessary at a minimum to: (a) invert the components of Williams (from concave to convex and convex to concave); (b) reconstruct the support structures 80 and 82 for the barrier plate 70 to enable the barrier plate to move toward or away from the cover member C (the upper barrier plate 70 is secured to cover member C and cannot move relative thereto); (c) put a gasket in recess 77 where none now exists and dispose the

gasket wholly within the recess; and (d) force the ridge 54 against the gasket in recess 77. Thus, in order for the ridge 54 and recess 77 to nest into a seal, the support structure would have to be re-engineered to perform a function it does not now perform and was never intended to perform. If anything, Williams teaches away from the two plates being able to compress a seal between them by teaching that they be maintained in a fixed, spaced-apart relationship.

Williams teaches that no seal is required between ridge 54 and recess 77. A further instance of Williams teaching away from Applicant's invention. This not a case of supplying Williams with a different seal than that disclosed. This is a case where no seal is disclosed or even indicated as necessary. There is nothing that makes it obvious to supply Williams with an element it does not now have or teach is necessary or even desirable.

### **Lorenz '311**

Lorenz is cited for combination with Williams to supply missing element (c) above — a gasket secured wholly within said vent recess where it is protected against damage. For the reasons given below, Lorenz does not disclose the limitation and its combination with Williams is ineffective and improper even under the relaxed standards of KSR.

In evaluating Lorenz, it is critical that the limitation against which it is cited be fully considered. The limitation in question is more than just a gasket secured wholly within a recess. The limitation is a gasket secured wholly within a recess where the recess is in an interior surface of a planar member that contains a vent and that, along with other planar members, encloses an

interior space in a sterilization container. Lorenz does not teach any of these claim limitations, the assertions in the Office Action to the contrary notwithstanding.

The application of Lorenz as set forth at pages 5 and 6 of the Office Action is factually defective for the following reasons: (1) reference to Fig. 5 is to an embodiment that employs a valve 20 and not a filter, so it does not correspond to Applicant's invention; (2) the planar surface 48 of Lorenz '311 does not include the vent 16; (3) the sheet filter 18 is on the exterior of the space enclosed by the planar member that includes the vent 16, not the interior; (4) the element designated "50" is a "flat peripheral segment" (Col. 4, line 67) separate from the vent 16 and thus not a vent recess or even a recess of any kind; (5) the element 50 which the Examiner calls "an interior container planar surface" is not in the same planar surface as the vent 16; (6) rigid frame 48 is not an interior planar surface that encloses the interior space of the container; (7) the element 14 that is called a "filter cover" in the Office Action is, according to Lorenz, an "intermediate cover" in which the vent (holes) 16 reside, there is no filter cover as such in Lorenz; (8) the flat segment 24 (Col. 4, lines 2-3) is designated in the Office Action as both a "seal ridge" and a "vent recess" (page 6) when it is neither — it's flat; and (9) the gasket 52 is not wholly within any recess, but rather sits on top of flat element 24 where it is fully exposed.

Thus, there is nothing in Lorenz that one skilled in the art would find to add to Williams that would result in Applicant's invention as claimed in claim

1. If the seal of Lorenz were somehow (and it's not clear at all how this could be done) transplanted to Williams where no seal now exists, Applicant's invention would not realized.

***KSR International v. Teleflex Inc.* 550 U.S.\_\_\_\_ (2007) (KSR)**

KSR may have relaxed the standards for determining obviousness, but, at the same time, it underscores the necessity for the legal conclusion of obviousness to be more than mere speculation or an unsupported subjective conclusion, as made clear from the following quotes from KSR:

("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".)

"As is clear from cases such as Adams, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."

"It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."

"See Graham, 383 U. S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight" (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964)))."

**Conclusion**

Applicant has reduced the number of claims and amended the remaining claims to overcome the objections and more precisely define the invention over the patents to Williams '913 and Lorenz '311 cited for the first time in the current Office Action.




As demonstrated above, the combination of Williams and Lorenz does not arrive at Applicant's claimed invention and goes far beyond what is considered "obvious" even under the standards announced in the recent Supreme Court decision in *KSR*.

Thus, Applicant requests that the amendments be entered and the claims allowed.

Respectfully Submitted,

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